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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,139

05/19/2006

Leon Rudakov

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT

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3773

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12/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,139	Applicant(s) RUDAKOV ET AL.	
	Examiner DIANNE DORNBUSCH	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-13, 15-17, 19-22, 24-36, 39-45, 47-56 and 58-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-13, 15-17, 19-22, 24-36 39-45, 47-56, and 58-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/31/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-5,7-13,15-17,19-22,24-36,39-45,47-56 and 58-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 34, 41, 72, 77, and 78 states that the distance between adjacent pores is less than about 75 microns. This is indefinite because the pore distance should be less than 75 microns not about 75 microns because than it could be 75.5 or 76 which would be greater than 75 microns.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-13, 15-22, 24-31, 35, 36, 41-56, 58-69, 73, 74, 77, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Sridharan et al. (2003/0124279).

Claims 1, 2, 5, 20-22, 41, 42, 45, 59-61, 77, and 78:

Rudakov discloses a medical device (11) for insertion into a bodily vessel, the device comprising: a mechanically expandable device (16) expandable from a first

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position to a second position (Col. 5 Lines 15-17), such that in the second position, an exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel (Col. 5 Lines 13-17). The mechanically expandable device (16) is engaging through the vessel by expanding radially and providing the rigidity on the top sleeve (13) in order to maintain contact with the vessel.

Furthermore Rudakov discloses that a porous membrane expandable (12, 13) (Col. 2 Line 16) in response to expansion of the mechanically expandable device (16) (Col. 5 Lines 15-17); wherein at least a portion of the membrane is secured to the mechanically expandable (the membrane is attached to the mechanically expandable device by using rings 17 and by everting the membrane in order to hold the mechanical expandable device as disclosed in the Col. 3 Lines 48-65), such that a proximal end of the membrane is proximate to a proximal end of the mechanically expandable device, and a distal end of the membrane is proximate to a distal end of the mechanically expandable device (Col. 3 Lines 48-65); and wherein the membrane has a porosity over a length extending from the distal end of the membrane to the proximal end of the membrane (the membrane is made of a material which contains pores throughout the material in order to optimize desired biological responses; wherein when the mechanically expandable device is expanded in the bodily vessel, adjacent to the aneurysm, the membrane is effective to: obstruct blood flow from the vessel into the aneurysm (the device can be placed in a vessel to treat an aneurysm by placing it between the opening where part of the device is covering the aneurysm thereby

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obstructing the flow by using the porous membrane); and permit blood flow through pores in the membrane and into branch vessels arising from the bodily vessel.

With respect to the statements of what the membrane is effective to do (capable of), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Additionally, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Rudakov further discloses that the membrane (12, 13) can be made of ePTFE as well as the membrane having pores between 20 to 100 microns in size (Col. 2 Lines 28-29).

Rudakov teaches all the claimed limitations discussed above however, Rudakov does not specify that the membrane has a substantially uniform porosity and the distance between adjacent pores of the membrane being less than 75 microns.

Sridharan discloses a ePTFE membrane (10) which has a uniform porosity as seen in Fig. 1) where each pore size is between 20-200 microns and the distance between adjacent pores is less than 75 microns ([0031]) as well as the membrane comprising a mesh (Fig. 1).

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It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov with a uniform porosity in view of the teachings of Sridharan, in order to promote cell in growth as well as reducing the risk of embolic release through out the length of the device equally.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the distance between adjacent pores less than 75 microns in view of the teachings of Sridharan, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Note that the combination of Rudakov in view of Sridharan will allow the membrane to be placed on the aneurysm and obstruct flow through the aneurysm as well as permitting flow through the pores in the branch vessels that are covered by the membrane since it will contain the specific pore size and the specific length between each adjacent pore that provides the function as recited in the claim.

Claims 3 and 43: Rudakov discloses that the membrane (12, 13) is made of a biocompatible and elastomeric polymer (Col. 2 Lines 10-21).

Claims 4 and 44: Rudakov discloses that the membrane (12, 13) has a thickness of about 0.0005 to 0.005" (Col. 2 Lines 22-25).

Claims 7 and 47: Rudakov discloses that the membrane (12, 13) is made from polymeric material (Col. 2 Lines 10-13).

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Claims 8 and 48: Rudakov discloses that the polymeric material forms multiple sub-layers mixed with drugs or reagents (Col. 3 Lines 26-29 and Col. 4 Lines 41-43 and Lines 58-61). The layers are formed by each of the coatings on the membrane.

Claims 9 and 49: Rudakov discloses that the membrane (12, 13) is capable of isotropic expansion (Col. 5 Lines 13-17).

Claims 10 and 50: Rudakov discloses that the membrane (13) is disposed on the exterior surface of the device (16) (Col. 2 Lines 4-5 and Fig. 1).

Claims 11 and 51: Rudakov discloses that the membrane (12, 13) completely surrounds the device (Col. 3 Lines 52-58). There is only one material use to form the outer membrane (13) and the inner membrane (12) which surrounds the device (16) as disclosed in the method of manufacturing in Col. 3 Lines 42-67.

Claims 12 and 52: Rudakov discloses that the membrane (12, 13) circumferentially surrounds a portion of the device (Fig. 2 and Col. 3 Lines 48-65).

Claims 13 and 53: Rudakov discloses that the membrane (12, 13) covers a portion of the device (Fig. 2).

Claims 15 and 54: Rudakov discloses a membrane is made from a solid polymer (Col. 2 Lines 10-13). The polymer is solid since it has three dimensions (length, breadth, and thickness) (Col. 2 Lines 22-25 and Fig. 1-4).

Claims 16, 17, 55, and 56:

Rudakov discloses each and every structural element of the membrane set forth in claims 16 and 17 (Col. 2 Lines 28-29).

Rudakov teaches that the membrane comprises pores between 20 to 100 microns in size (Col. 2 Lines 28-29), but is silent as to the method of making the pores. The claimed phrase "fabricated pores" and "fabricated by laser drilling" are being treated as a product by process limitation; that is, that the pores are made by laser drilling. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Claims 19 and 58: Rudakov discloses that the membrane (12, 13) comprises a plurality of polymeric strips (17) (Col. 2 Lines 55-58) secured to the mechanically expandable device (16) (Col. 2 Lines 5-6 and 63-64).

Claims 24 and 62: Rudakov discloses that the mechanically expandable device (16) comprises a generally tubular structure (Fig. 1) having an exterior surface defined by a plurality of interconnected struts (26 with 22 and 23) having interstitial spaces therebetween (Fig. 1).

Claims 25 and 63: Rudakov discloses the mechanically expandable (16) device is balloon expandable (Col. 5 Lines 13-17).

Claims 26 and 64: Rudakov discloses that the mechanically expandable device (16) is a stent (Fig. 1). Figure 1 shows that the expandable device (16) has the structure of a stent as well as Rudakov discloses that the final product is a stent-graft where the expandable device (16) is the stent and the graft is the membrane (12, 13).

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Claims 27 and 65: Rudakov discloses that the membrane (12, 13) is supported by the generally tubular structure (Fig. 1) and is attached to at least one strut (26) as seen in Fig. 1-3 as well as in the explanation of the manufacturing process (Col. 4 Lines 1-14) where the membrane (12, 13) are placed on the expandable device (16).

Claims 28 and 66: That the membrane (12, 13) is tubular (Fig. 1-2) and wherein the membrane (30) is disposed onto the outer surface of the stent (Fig. 1-2).

Claims 29 and 67: That the membrane (12, 13) is a segment of a tubular structure (Fig. 1-2) disposed onto a portion of the outer surface of the stent (Fig. 1-2).

Claims 30 and 68: Rudakov discloses that the at least one drug or reagent is in any one form selected from the group consisting of: solid tablet, liquid and powder (Col. 4 Lines 36-49).

Claims 31 and 69: Rudakov discloses that at least one radiopaque marker is provided on the mechanically expandable device (16) to improve visibility of the device during and after insertion (Col. 4 Lines 17-21).

Claims 35, 36, 73, and 74: Rudakov discloses a method of manufacturing comprising: disposing the generally tubular structure on a mandrel (51); and disposing the membrane (12,13) onto the outer surface of the mechanically expandable device (16). The device has two membranes, where the first membrane (12) is first disposed on the mandrel (51) and then the expandable device/stent (16) is placed on the mandrel as well as the connecting rings (17). After this part the membrane (13) is placed on top of the mechanically expandable device/stent as it is disclosed in Fig. 3-4 and Col. 4 Lines 1-14.

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5. Claims 34, 39, 40, 72, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al. (5,948,018) in view of Sridharan et al. (2003/0124279).

Claims 34 and 72:

Dereume discloses a medical device for treating a bifurcation or trifurcation intracranial aneurysm between at least two bodily vessels, the device comprising: a first mechanically expandable device (57), expandable from a first position to a second position (Fig. 9-13), such that, in the second position, an exterior surface of the first mechanically expandable device engages with an inner surface of a first branch vessel arising from a parent vessel so as to maintain a fluid pathway through the first branch vessel (Fig. 13); a second mechanically expandable device (55, 56), expandable from a first position to a second position (Fig. 9-13), such that, in the second position, an exterior surface of the second mechanically expandable device engages with an inner surface of a second branch vessel arising from the parent vessel so as to maintain a fluid pathway through the second branch vessel (Fig. 13). The mechanically expandable devices are engaging through the vessel by expanding radially and providing the rigidity on the top membrane in order to maintain contact with the vessel.

Furthermore Dereume discloses a porous membrane (53, 54) (Claim 1 and 18) , and at least a portion of a proximate end of the membrane is secured to the first mechanically expandable device and a distal end of the membrane is secured to the second mechanically expandable device (Fig. 10); the membrane has a porosity over a length extending from a distal end of the membrane to a proximal end of the membrane

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(Fig. 10); and wherein, when the first mechanically expandable device is expanded in the first branch vessel adjacent to the aneurysm and the second mechanically expandable device is expanded in the second branch vessel adjacent to the aneurysm position (the device can be placed in a vessel to treat an aneurysm by placing it between the opening where part of the device is covering the aneurysm thereby obstructing the flow by using the porous membrane), the membrane is effective to at least partially obstruct blood flow into the aneurysm; and permit blood flow through pores in the membrane and into that blood supply to perforators and/or microscopic branches of brain arteries.

With respect to the statements of what the membrane is effective to do (capable of), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Additionally, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Dereume teaches all the claimed limitations discussed above however, Dereume does not specify that the membrane has a substantially uniform porosity and the distance between adjacent pores of the membrane being less than 75 microns.

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Sridharan discloses a ePTFE membrane (10) which has a uniform porosity as seen in Fig. 1) where each pore size is between 20-200 microns and the distance between adjacent pores is less than 75 microns ([0031]) as well as the membrane comprising a mesh (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dereume with a uniform porosity in view of the teachings of Sridharan, in order to promote cell in growth as well as reducing the risk of embolic release through out the length of the device equally.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the distance between adjacent pores less than 75 microns in view of the teachings of Sridharan, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Note that the combination of Dereume in view of Sridharan will allow the membrane to be placed on the aneurysm and obstruct flow through the aneurysm as well as permitting flow through the pores in the branch vessels that are covered by the membrane since it will contain the specific pore size and the specific length between each adjacent pore that provides the function as recited in the claim.

Claims 39 and 75: Dereume discloses that the membrane expands in response to expansion of the first mechanically expandable device (Fig. 9-13).

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Claims 40 and 76: Dereume discloses the method wherein the membrane expands in response to expansion of the first and second mechanically expandable devices (Fig. 9-13).

6. Claims 32, 33, 70, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Sridharan et al. (2003/0124279). and further in view of Dereume et al. (5,639,278).

Claims 32 and 70:

Rudakov in view of Sridharan teaches all the claimed limitations discussed above however, Rudakov in view of Sridharan does not disclose that at least one radiopaque marker is made from gold or platinum.

Dereume discloses that at least one radiopaque marker is made from gold or platinum (Col. 14 Lines 44-46).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Sridharan with a radiopaque marker made of gold or platinum in view of the teachings of Dereume, since this materials are well known in the art to be used as radiopaque markers.

Claims 33 and 71:

Rudakov discloses that there is a radiopaque marker at the end of the expandable device (Col. 4 Lines 17-19).

Rudakov in view of Sridharan teaches all the claimed limitations discussed above however, Rudakov in view of Sridharan does not disclose that there is radiopaque marker at the center of the expandable device.

Dereume discloses that there is radiopaque marker at the center of the expandable device (Col. 14 Lines 38-44). The radiopaque marker is placed in the bifurcation area which is at the center of the mechanical expandable device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Sridharan with a radiopaque marker at the center of the device in view of the teachings of Dereume, in order to provide visualization of the graft and specifically of the area where the bifurcation or aneurysm is located.

Response to Arguments

7. Applicant's arguments filed September 1, 2009 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773

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